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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 05/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/717,296	DILLON ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 9-13 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 9-13 and 17 have not been further treated on the merits.

Election/Restrictions

2. Each Group detailed below reads on patentably distinct Groups drawn to multiple SEQ ID Numbers. The sequences are patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid or nucleic acid sequences, the Applicants must further elect a single amino acid or a single nucleic acid sequence (See MPEP 803.04).

3. It is noted that the restriction Groups are set forth as Groups I-VI for convenience. However, each restriction Group actually comprises the numbers of Groups which read on each patentably distinct nucleic acid, polypeptide, fusion protein or antibody specificity.

4. In addition, it is noted that claim 7, drawn to a fusion protein comprising at least one polypeptide according to claim 2 would be subject to further restriction, as each fusion protein comprising more than one polypeptide would differ in structure and modes of action to such extent as to be considered patentably distinct.

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 4, 8 and 15, drawn to an isolated polynucleotide comprising a sequence provided in SEQ ID NO: 52, 74, 83, 1 54, 302-305 and 312,

oligonucleotide that hybridizes to it and a kit comprising the polynucleotide, classified in class 536, subclass 23.1, and in class 435, subclass 810, for example.

II. Claim 2 drawn to an isolated polypeptide comprising a sequence provided in SEQ ID NO: 306-311 and 313, classified in class 530, subclass 300, for example.

III. Claims 5 and 16, drawn to an antibody to a polypeptide and a kit comprising the antibody, classified in class 530, subclass 387.1, and in class 435, subclass 810, for example.

IV. Claim 6, drawn to a method for determining the presence or absence of cancer in a patient, comprising contacting a biological sample obtained from a patient with a binding agent which binds to the polypeptide, classified in class 435, subclass 7.1, for example.

V. Claim 7, drawn to a fusion protein, classified in class 536, subclass 23.4.

VI. Claim 14, drawn to a method for determining the presence of cancer in a patient, comprising contacting a biological sample obtained from a patient with an oligonucleotide, class 435, subclass 6, for example.

The inventions are distinct, each from the other because of the following reasons:

6. Inventions I and (II and V) are separate and distinct because the inventions are directed to different chemical types regarding the critical limitations therein. For Groups II and V, the critical feature is a polypeptide whereas for Group I the critical feature is a polynucleotide. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid

sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I does not necessarily encode a polypeptide of Group II. For example, as disclosed in the specification, SEQ ID NO: 306 is 220 amino acids in length, whereas the nucleic acid molecule of claim 1(c) requires only 20 nucleotides (which would encode at most a polypeptide of 6 amino acids in length). Similarly, the nucleic acid molecule of claim 1(b) is complementary to the coding sequence, and therefore would not encode the polypeptide of Group II. Furthermore, the information provided by the polynucleotide of Group I can be used to make a materially different polypeptide than that of Group II. For example, a nucleic acid which hybridizes to SEQ ID NO: 52, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO: 306. In addition, while a polypeptide of Group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of Group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. Finally, the fusion polypeptide of Group V is different from polypeptides of Group II in that it contains additional amino acids which would not encode the fusion part. For these reasons, the inventions of Groups I and (II and V) are patentably distinct.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is

provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the polypeptide claims include polypeptides having 70% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1(c) would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group II. As such, it would be burdensome to search the inventions of Groups I and (II and V) together.

7. Inventions I and III are separate and distinct, as the claims of Invention I are drawn to polynucleotides, while the claims of Group III are drawn to an antibody. These are differing biochemical entities having differing biochemical properties, structures and effects. The polynucleotide of group I and the antibody of group III are patentably distinct for the following reasons. The antibody of group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of Group III which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any

relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I will not encode an antibody of Group III. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Group I and Group III would impose a serious search burden since a search of the polynucleotide of Group I would not be used to determine the patentability of an antibody of Group III, and vice-versa.

8. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polynucleotide of Group I is not required for the method of Group IV.

9. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I could be used for an entirely different purpose such as in making the polypeptide of Group II, rather than in the method of Group VI.

Searching the inventions of Groups I and VI together would impose serious search burden. The inventions of Groups I and VI have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of inhibiting the presence of cancer in a patient using oligonucleotides are not coextensive. Group I encompasses molecules which are claimed in terms of hybridization and percent identity in regard to reference sequence SEQ ID NO 52, for example, which are not required for the search of Group VI. In contrast, the search for Group VI would require a text search for the method of diagnosing autoimmune diseases in addition to an oligonucleotide search of fragments of SEQ ID No: 52, for example, or complements of fragments. Prior art which teaches a polynucleotide that is 70% identical to SEQ ID No 52 would not necessarily be applicable to the method of using the fragments of SEQ ID No 52. Moreover, even if the polynucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

10. Inventions (II and V) and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to polypeptides and antibodies recognizing the polypeptides. The polypeptides of Group II and V and the antibody of Group III are patentably distinct for the following reasons:

While the inventions of Groups II, V and Group III are polypeptides, in this instance the polypeptide of Group II is a single chain molecule that functions as an enzyme, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2

light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of Group II and the antibody of Group III are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of Group II is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group III is defined in terms of its binding specificity to a small structure within a given amino acid sequence. Furthermore, an antibody of Group III would not specifically bind all of the polypeptides of Group II or V because the polypeptides of Group II encompass fragments of full-length polypeptides, and therefore an antibody to a full-length polypeptide would not necessarily bind to a polypeptide fragment, and vice versa. Further, an antibody to a polypeptide or its fragment would not necessarily bind to a fusion protein. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of Groups II, V and Group III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel.

In addition, the technical literature search for the polypeptide of Group II or V and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

11. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in the production of antibodies of Group III, rather than for the method of Group IV.

Searching the inventions of Groups II and IV together would impose serious search burden. The inventions of Groups II and IV have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of detecting the presence of cancer using a polypeptide are not coextensive. Group II encompasses molecules which are claimed in terms of 70% or 90% identity to certain SEQ ID NOs, which are not required for the search of Group IV. In contrast, the search for Group IV would require a text search for the method of detecting the presence of cancer in addition to a search for the SEQ ID NOs. Prior art which teaches a polypeptide which is 70% identical to SEQ ID No 306, for example, would not necessarily be applicable to the method of using the polypeptide comprising SEQ ID No 306. Moreover, even if the polypeptide product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

12. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are a polypeptide and a fusion polypeptide, and these are two different entities with different functions and different modes of operation.

Even though the polypeptide of Group II and the fusion protein comprising the polypeptide of Group V are both proteins, search for these two would not be coextensive. For example, a fusion protein comprising SEQ ID NO: 306 or its fragments cannot be found just by searching for SEQ ID NO: 306 or its fragments. Further, since the fusion can be with any other protein, the number of records to search is extremely large, making the search burdensome.

13. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the polypeptide of Group II is not required for the method of Group VI.

14. Inventions III and (IV, VI) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the antibody of Group III is not required for the methods of Groups IV and VI.

15. Inventions (IV, VI) and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or

they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that the fusion polypeptide of Group V is not required for the methods of Groups IV VI.

16. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.

The instant specification does not disclose that these methods would be used together. The method of determining the presence of cancer using using a polypeptide (Group IV) and the method of determining the presence of cancer using using a polynucleotide (Group VI) are unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. For diagnosis using the polynucleotide, hybridization may be used. For diagnosis using the polypeptide, labeled antibody may be used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions IV and VI are patentably distinct.

17. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

18. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

19. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERESA STRZELECKA
PATENT EXAMINER

Teresa Strzelecka
5/13/06